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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re the Application of:

Group Art Unit: 1761

BARCLAY

Examiner: Anthony Weier

Serial No.: 08/918,325

Filed: August 26, 1997

Atty. File No.: 2997-1-2-1-1DIV

For: "MILK PRODUCTS HAVING HIGH
CONCENTRATIONS OF OMEGA-3
HIGHLY UNSATURATED FATTY
ACIDS"DECLARATION OF
WILLIAM R. BARCLAY
(under 37 CFR § 1.132)

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS
BEING DEPOSITED WITH THE UNITED STATES POSTAL
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ADDRESSED TO ASSISTANT COMMISSIONER FOR
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1999.

SHERIDAN ROSS P.C.

BY: _____

Assistant Commissioner
for Patents
Washington, D.C. 20231

I, William R. Barclay, declare as follows:

1. I graduated from St. Mary's College with a Bachelor of Science in Biology in 1971.
2. I graduated from the University of Wisconsin, Madison, with a Master of Science in Water Resource Management in 1974.
3. I graduated from the University of California, Davis, with a Doctor of Philosophy in Aquatic Ecology in 1981.
4. I was a Postgraduate Research biologist with Scripps Institution of Oceanography at the University of California, San Diego, from 1981-1982 where I conducted research on the production of polysaccharides by soil algae and on controlling the bioflocculation potential of microalgae.

5. I was a Postdoctoral Fellow with Cooperative Institute for Research in Environmental Science at the University of Colorado, Boulder, from 1982-1983 where I conducted research on the production of polysaccharides, phenolics and organosulfur compounds by microalgae.

6. I was a Staff Scientist from 1983-1986 and a Senior Scientist from 1986-1987 with Solar Energy Research Institute, Golden, Colorado, where I developed technology to produce liquid fuels from microalgae biomass.

7. I am currently Chief Scientific Officer for OmegaTech, Inc. and was President and Director of Research for OmegaTech, Inc. from 1987 to 1997, during which time I isolated and developed microbial strains for use in the production of omega-3 highly unsaturated fatty acids.

8. I am the inventor of the above-identified application and have reviewed the Office Action having a mailing date of December 10, 1998.

9. I understand that the Examiner has rejected Claims 29-51 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,133,963, issued to Ise (the "Ise patent") or STN Database, AN 88:13222 Biobusiness for Milchwissenschaft, Vol. 43, No. 3, pp. 153, 155-158 by Hagemeister et al. (the "Hagemeister abstract"). The purpose of this Declaration is to demonstrate, using the results of experimental tests, that the products produced

according to the present invention are different from those of the cited references.

10. I have reviewed the Ise patent and the Hagemeister abstract, a copy of which was provided by the Examiner in the Office Action having a mailing date of April 10, 1998.

11. The Hagemeister abstract discloses infusing 220-420 g of menhaden oil per day for 28 and 43 days to 2 lactating cows which resulted in the transfer of 35-40% of the infused omega-3 fatty acid to milk fat; however, the Hagemeister abstract cited by the Examiner does not disclose any other fatty acid profile of the milk.

12. I have had research conducted in order to find information regarding the fatty acid profile of milk for cows which had been fed fish oil. Dr. Andrea LaCorte and Mr. Amos Morani of NutriStar (Via Vertoiba, 12/1 - Reggio Emilia - Italy) had these trials conducted to compare production of milk from cows fed microorganisms of the present invention as compared to cows fed tuna oil (tuna oil is richer in DHA than most fish oils such as menhaden oil).

13. Table 1 below shows the results obtained regarding the fatty acid composition comparison between milk produced from cows fed tuna oil, which has higher amount of DHA than menhaden oil, and milk produced from cows according to the present invention. The target amount of DHA fed to cows in each case was about 30 g per

cow per day. However the tuna oil fed cows exhibited an early decrease in feed intake due to the presence of the tuna oil.

Table 1. Selected fatty acid as percent of total fatty acid in milk produced from cows fed with tuna oil and microbial organisms of the present invention.

Fatty acid	Tuna oil		Present Invention	
	Control	12 days of feeding	Control	14 days of feeding
C20:1	<0.1	0.00	<0.1	0.11
C20:2	0.95	1.2	0.58	0.69
C20:4+C22:1	0.23	0.25	0.29	0.34
C20:5 n3 (EPA)	0.00	0.05	<0.1	<0.1
C22:5 n6 (DPA)	0.00	0.00	0.00	0.18
C22:6 n3 (DHA)	0.00	0.07	0.00	0.33
Total long chain n-3	0.00	0.12	0.00	0.33
Total long chain n-6	0.23	0.25	0.29	0.52

numbers represents % of total fatty acid.

14. As Table 1 clearly shows, the fatty acid content of the milk from cows fed fish oil is different from the fatty acid content of the milk from cows fed microorganisms of the present invention. Milk from cows fed microorganisms of the present invention contained both more long chain omega-6 and long chain omega-3 fatty acids.

15. In addition, fish oils, such as tuna oil and menhaden oil, do not contain any significant amount of docosapentaenoic acid (DPA, 22:5 n-6, an omega-6 fatty acid) compared to the microorganisms of the present invention; therefore, as shown in

Table 1, the milk from cows fed fish oils do not contain any appreciable amount of DPA. In contrast, milk product of the present invention has an increased amount of DPA n-6 (and slightly increased ARA n-6 (C20:4n-6) due to retroconversion from DPA n-6) in the milk because microbial organisms of the present invention contain DPA n-6.

16. Another set of comparison data showing the fatty acid composition in milk for cows fed menhaden type fish oils and cows fed microorganisms of the present invention was also obtained for OmegaTech by Dr. Andrea LaCorte and Mr. Amos Morani of NutriStar (Via Vertoiba, 12/1 - Reggio Emilia - Italy). The results are shown in Table 2.

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Table 2. Selected fatty acid as percent of total fatty acid in milk produced from cows fed with fish oil and microbial organisms of the present invention.

Fatty acid	Fish oil		Present Invention	
	Feeding protocol #1	Feeding protocol #2	Control	14 days of feeding
C20:1	0.38	0.21	<0.1	0.11
C20:2	0.21	0.26	0.58	0.69
C20:4+C22:1	0.11	0.23	0.29	0.33
C20:5 n3 (EPA)	0.39	0.31	<0.1	<0.1
C22:5 n6 (DPA)	N.D.	0.05	0.00	0.18
C22:6 n3 (DHA)	0.23	0.39	0.00	0.33
Total long chain n-3	0.62	0.70	0.00	0.33
Total long chain n-6	0.11	0.28	0.29	0.51

numbers represents % of total fatty acid.
N.D. = not detected

17. Although the amount or the time of feeding is not provided for the two fish oil feeding protocols, based on the amount of DHA present in the milk, it is believed that feeding protocol #2 was for a longer feeding period.

18. As Table 2 shows, even if the milk from fish oil fed cows contains a similar amount of DHA, the amount of total long chain omega-6 fatty acids (C20:4 n6+C22:5 n6) present in the milk produced by cows fed fish oils is significantly lower. Thus, when the amount of fish oil fed to a milk-producing animal is adjusted to provide the milk with a similar DHA fatty acid content, the total long chain omega-6 fatty acid content, e.g., DPA n6 + ARA n6,

is not similar or equal to that of the milk of the present invention.

19. The Ise patent discloses feeding an omega-3 fatty acid source in conjunction with vitamin E and water which contains silicic acid, glucanase, cellulase, calcium and phosphorus. See, for example, abstract, Claim 1, Col. 6, lines 65-66, and Col. 7, lines 3-15.

20. Similar to the Hagemeister abstract, the Ise patent uses fish oil, particularly menhaden oil. See Col. 5, lines 54-57. Therefore, the fatty acid composition of the milk product derived from the teachings of the Ise patent is different from the fatty acid composition of the milk product derived from the present invention for the reasons stated above in paragraphs 13-18.

21. It is known that in some cases feeding fish oil to lactating cows produces milk having a fishy odor and/or taste. See for example, Lacasse, et al., *J. Anim. Sci.* Vol. 76, Suppl. 1/*J. Dairy Sci.*, Vol 81, Suppl. 1/1998, page 231, abstract number 901, a copy of which was submitted previously. See also Long, PCT Publication No. WO 89/00606, which was cited by the Examiner.

22. In contrast, there is no "fishy" odor or taste present in the milk product of the present invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and

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belief are believed to be true; and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the subject application or any patent issuing thereon.

Date:

June 9, 1999

By:

William R. Barclay
William R. Barclay

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